



PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants:	Sosnowski et al.	Examiner:	Unassigned (Parent Application Examiner: S.A. Jiang)
Serial No.:	10/601,941	Group Art Unit:	Unassigned (Parent Application Group Art Unit: 1617)
Filed:	June 23, 2003	Docket No.:	1107-3 CIP
Confirmation No.:	7846	Customer No.:	33769
For:	Composition And Method For Reducing The Risk Or Progression Of Cardiovascular, Glaucoma And Tardive Dyskinesia Diseases	Dated:	October 6, 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

*I hereby certify this correspondence is being deposited  
with the United States Postal Service as first class mail,  
postpaid in an envelope, addressed to:  
Commissioner for Patents, P.O. Box 1450,  
Alexandria, Virginia 22313-1450*

on October 6, 2003  
Signed: Beth Jahrmarkt  
Beth Jahrmarkt

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In order to fulfill the requirements of candor and good faith set forth in 37 C.F.R.  
§1.56, Applicants submit herewith the following Information Disclosure Statement in  
accordance with the provisions of 37 C.F.R. §1.97 and §1.98.

### **UNITED STATES PATENTS**

<b><u>PATENTEE</u></b>	<b><u>PATENT NO.</u></b>	<b><u>ISSUE DATE</u></b>
Fogel	5,866,585	Feb. 2, 1999
Wakat	6,054,128	Apr. 25, 2000
Lipton et al.	5,922,773	Jul. 13, 1999
Rosenquist et al.	6,025,369	Feb. 15, 2000

### **FOREIGN DOCUMENTS**

<b><u>INVENTOR</u></b>	<b><u>PUBLICATION NO.</u></b>	<b><u>PUBLICATION DATE</u></b>
Henderson, Janeel	WO 00/37087 A1	June 29, 2000

### **NON-PATENT PUBLICATION**

Bucci, L.R., FDA filing reference, August 27, 1999, pp.1 and 2.

Pei I. Ho et al., *Multiple Aspects of Homocysteine Neurotoxicity: Glutamate Excitotoxicity, Kinase Hyperactivation and DNA Damage*, Journal of Neuroscience Research 70:694-702 (December, 2002).

Seshadri, S. et al., *Plasma Homocysteine as a Risk Factor for Dementia and Alzheimer's Disease*, 1: N Engl J Med. 2002 Feb 14; 346(7):476-83.

Fonseca, V.A. et al., *Insulin Sensitivity and Plasma Homocysteine Concentrations in Non-Diabetic Obese and Normal Weight Subjects*, Atherosclerosis, 2003 March; 167(1):105-9.

A. Ambrosch et al., *Relation Between Homocysteinaemia and Diabetic Neuropathy in Patients with Type 2 Diabetes*, Diabetic Medicine, Volume 18, Issue 3, p.185, March 2001.

Pamela Moore et al., *Apoptotic Cell Death in the Mouse Retinal Ganglion Cell Layer is Induced in Vivo by the Excitatory Amino Acid Homocysteine*, Exp Eye Res. 73(1), pp. 45-57, July, 2001, Academic Press.

Centrum references, Whitehall Robins: *Centrum Focused Formulas Heart and Centrum Herbals Ginkgo*, from [www.centrum.com](http://www.centrum.com).

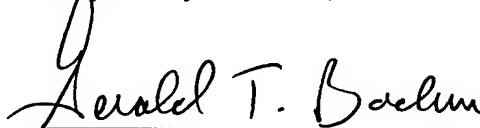
McCully, Kilmer S., M.D., *The Homocysteine Revolution "A Bold New Approach to the Prevention of Heart Disease"*, Keats Publishing, Los Angeles 1997, pp. 33, 64-65, 92-105, 137, 181.

Bleich S., Degner, D., Bandelow, B., von Ahsen, N., Ruther, E., Kornhuber, J., *Plasma Homocysteine is a Predictor of Alcohol Withdrawal Seizures*, Neuroreport 2000, Aug. 21 Abstract.

The above-referenced documents are listed on PTO Form 1449. We have enclosed the cited documents to facilitate reference to them.

Applicants are not aware of any other references to be identified at this time. If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicants' attorney at the telephone number set forth below.

Respectfully submitted,

A handwritten signature in black ink, reading "Gerald T. Bodner", written over a horizontal line.

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Attorney for Applicants

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GTB/bj



FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
(Rev. 2-32) PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.  
1107-3 CIP

SERIAL NO.  
10/601,941

APPLICANT  
Sosnowski, et al.

CUSTOMER NO.  
33769

FILING DATE  
June 23, 2003

GROUP ART UNIT  
Unassigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
		5,866,585	2/2/99	Fogel			
		6,054,128	4/25/00	Wakat			
		5,922,773	7/13/99	Lipton et al.			
		6,025,369	2/15/00	Rosenquist et al.			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
							YES	NO
		WO 00/37087 A1	6/29/00	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

			Bucci, L.R., FDA filing reference, August 27, 1999, pp. 1 and 2.
			Pei I. Ho et al., <i>Multiple Aspects of Homocysteine Neurotoxicity: Glutamate Excitotoxicity, Kinase Hyperactivation and DNA Damage</i> , <i>Journal of Neuroscience Research</i> 70:694-702 (December, 2002). ✓

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.

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		Seshadri, S. et al., <i>Plasma Homocysteine as a Risk Factor for Dementia and Alzheimer's Disease</i> , 1: N Engl J Med. 2002 Feb 14; 346(7):476-83. ✓
		Fonseca, V.A. et al., <i>Insulin Sensitivity and Plasma Homocysteine Concentrations in Non-Diabetic Obese and Normal Weight Subjects</i> , Atherosclerosis, 2003 March; 167(1):105-9. ✓
		A. Ambrosch et al., <i>Relation Between Homocysteinaemia and Diabetic Neuropathy in Patients with Type 2 Diabetes</i> , Diabetic Medicine, Volume 18, Issue 3, p.185, March 2001. ✓
		Pamela Moore et al., <i>Apoptotic Cell Death in the Mouse Retinal Ganglion Cell Layer is Induced in Vivo by the Excitatory Amino Acid Homocysteine</i> , Exp Eye Res. 73(1), pp. 45-57, July, 2001, Academic Press. ✓
		Centrum references, Whitehall Robins: <i>Centrum Focused Formulas Heart and Centrum Herbals Ginkgo</i> , from www.centrum.com.
		McCully, Kilmer S., M.D., <i>The Homocysteine Revolution "A Bold New Approach to the Prevention of Heart Disease"</i> , Keats Publishing, Los Angeles 1997, pp. 33, 64-65, 92-105, 137, 181. ✓
		Bleich S., Degner, D., Bandelow, B., von Ahsen, N., Ruthner, E., Kornhuber, J., <i>Plasma Homocysteine is a Predictor of Alcohol Withdrawal Seizures</i> , Neuroreport 2000, Aug. 21 Abstract.

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